REMARKS

Claims 3, 4, 7-10 and 17 were examined in the Final Office Action dated July 17, 2002 and rejected under 35 U.S.C. §112 first and second paragraphs. Applicants note with appreciation the withdrawal of the previous objection to the specification and the withdrawal of the rejections under 35 U.S.C. §112, first and second paragraphs for use of the term "functionally equivalent fragment." However, the Office has maintained the above-stated rejections based on the recitation "functionally equivalent variant." Applicants assert for reasons of record that the previous claims are indeed enabled, definite and are adequately supported. Nevertheless, in an effort to advance prosecution, the term "variant" has now been eliminated from the claims. Amendment of the claims is made without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Claims 3, 4, 7-10 and 17 are therefore allowable.

New claims 21-23 are also allowable. Claims 21 and 22 are similar to claims 4 and 10, respectively, with the initial contacting step eliminated, as the step is not essential to the invention. New claim 23 depends from claim 22 and recites that the mammalian cells are MOLT-4 cells. Support for the new claims can be found in the claims as originally filed as well as throughout the specification, e.g., in the examples.

The Title has also been amended to more clearly track the invention now claimed.

CONCLUSION

Applicants respectfully submit that the claims are novel and nonobvious over the art and comply with the requirements of 35 U.S.C. §101 and §112. Accordingly, allowance is believed to be in order and an early notification to that effect would be appreciated.

Please direct all further communications in this application to:

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 4, 10 and 17 have been amended as follows:

4. (Four times amended) A process for the preparation of a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, or for the preparation of a functionally equivalent [variant or] fragment thereof, comprising the steps of:

i) contacting cells with a preparation of E2;

ii) obtaining a membrane preparation from cells exhibiting binding to E2; and

iii) purifying said protein from said preparation.

10. (Three times amended) A process for the preparation of a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, or a functionally equivalent [variant or] fragment thereof, comprising the steps of:

i) contacting mammalian cells with a preparation of E2;

ii) obtaining a membrane preparation from the mammalian cells selected for binding to E2;

iii) precipitating the preparation with ammonium sulphate at less than 33% saturation and retaining the supernatant;

iv) precipitating the supernatant with ammonium sulphate at between 33 and 50% saturation and retaining the precipitate;

v) resuspending the precipitate from step iv) in buffer and subjecting the resuspended precipitate to hydrophobic interaction chromatography.

17. (Twice amended) A diagnostic kit comprising a protein having a molecular weight of about 24 kd, which specifically binds to the E2 protein of hepatitis C virus, or a functionally equivalent [variant or] fragment thereof.

The following new claims have been added:

--21. (New) A method for preparing a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, or for preparing a functionally equivalent fragment thereof, comprising the steps of:

i) obtaining a membrane preparation from cells that bind to E2; and

ii) purifying said protein from said preparation.

22. (New) A method for preparing a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, comprising the steps of:

i) obtaining a membrane preparation from mammalian cells that bind to E2;

ii) adding ammonium sulphate to said preparation at less than 33% saturation to produce a precipitate and a supernatant;

iii) adding ammonium sulphate to said supernatant at between 33 and 50% saturation and retaining the precipitate;

iv) resuspending the precipitate from step iii) in buffer and subjecting the resuspended precipitate to hydrophobic interaction chromatography; and

v) recovering said protein.

23. The process of claim 22 wherein said mammalian cells are MOLT-4 cells.--

The Title has been amended as follows:

<u>METHOD FOR PREPARING HCV E2</u> BINDING PROTEIN.

CURRENTLY PENDING CLAIMS

3. (Twice amended) The process of claim 4, wherein the protein is a transmembrane protein.

4. (Four times amended) A process for the preparation of a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, or for the preparation of a functionally equivalent fragment thereof, comprising the steps of:

i) contacting cells with a preparation of E2;

ii) obtaining a membrane preparation from cells exhibiting binding to E2; and

iii) purifying said protein from said preparation.

7. (Amended) A process according to any one of claims 2-4 wherein the preparation is purified by ammonium sulphate precipitation employing ammonium sulphate at between 33 and 50% saturation.

8. (Amended) A process according to any one of claims 2-4 further comprising at least one hydrophobic interaction chromatography procedure.

9. (Amended) A process according to any one of claims 2-4 further comprising at least one acetone precipitation procedure.

10. (Three times amended) A process for the preparation of a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, or a functionally equivalent fragment thereof, comprising the steps of:

i) contacting mammalian cells with a preparation of E2;

ii) obtaining a membrane preparation from the mammalian cells selected for binding to E2;

iii) precipitating the preparation with ammonium sulphate at less than 33% saturation and retaining the supernatant;

iv) precipitating the supernatant with ammonium sulphate at between 33 and 50% saturation and retaining the precipitate;

v) resuspending the precipitate from step iv) in buffer and subjecting the resuspended precipitate to hydrophobic interaction chromatography.

17. (Twice amended) A diagnostic kit comprising a protein having a molecular weight of about 24 kd, which specifically binds to the E2 protein of hepatitis C virus, or a functionally equivalent fragment thereof.

21. (New) A method for preparing a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, or for preparing a functionally equivalent fragment thereof, comprising the steps of:

i) obtaining a membrane preparation from cells that bind to E2; and

ii) purifying said protein from said preparation.

22. (New) A method for preparing a protein having a molecular weight of about 24kd which specifically binds to the E2 protein of hepatitis C virus, comprising the steps of:

i) obtaining a membrane preparation from mammalian cells that bind to E2;

ii) adding ammonium sulphate to said preparation at less than 33% saturation to produce a precipitate and a supernatant;

iii) adding ammonium sulphate to said supernatant at between 33 and 50% saturation and retaining the precipitate;

iv) resuspending the precipitate from step iii) in buffer and subjecting the resuspended precipitate to hydrophobic interaction chromatography; and

v) recovering said protein.

23. The process of claim 22 wherein said mammalian cells are MOLT-4 cells.